FDA – Industry MDUFA VI Reauthorization Meeting
February 11, 2026, 9:00 am – 1:00 pm EST
FDA White Oak Building 66, Silver Spring, MD
Room 4404

Purpose: To discuss MDUFA VI reauthorization.

Attendees

FDA
Eli Tomar, *CDRH*
Owen Faris, *CDRH*
Barbara Marsden, *CDRH*
Jonathan Sauer, *OO*
Kathryn Capanna, *CDRH*
Malcolm Bertoni, *Consultant*
Cherie Ward-Peralta, *CBER*
Virginia Knapp Dorell, *OCC*
Alexandra Hauke, *CDRH*
Thomas Szivos, *CDRH*
Sara Doll Aguel, *CDRH*
Stephen Sobieski, *Consultant*
Corina Ploscaru, *Consultant*
Lisa Lim, *CDRH*
Linda Ricci, *CDRH*
Marta Gozzi, CDRH
Susannah Gilbert, CDRH
Daniel Caños, *CDRH*
Rebecca Torguson, *CDRH*

Industry
April Veoukas, *Abbott*
Geeta Pamidimukkala, *AdvaMed*
Josh Silverstein, *Stryker*

AdvaMed Team
Zach Rothstein, *AdvaMed*
Diane Wurzburger, *GE Healthcare*
Yarmela Pavlovic, *Medtronic*

MDMA Team
Mark Leahey, *MDMA*
Melanie Raska, *Boston Scientific*
Nicole Zuk, *Siemens Healthineers*
April Lavender, *Cook Medical*

Meeting Start Time: 9:00 am EST

Opening, FDA Feedback on Industry Proposals
FDA presented feedback on Industry proposals related to consensus standards and other topics from previous meetings. FDA confirmed support for Industry's proposal for advancing consensus standards with minor revisions. FDA and Industry expressed support for the Consensus Standards proposal.

FDA provided feedback on Industry's proposal on periodic reporting to include staffing levels by office within CDRH, proposing instead to do center level reporting consistent with the other FDA centers. Industry reaffirmed the importance of reporting at the office level, which FDA agreed to take back for further consideration. This topic will require further discussion.

FDA also agreed to a commitment to hire consistent with the agreement and proposed reverting to language similar to the MDUFA IV Commitment Letter regarding hiring commitments, which Industry indicated support for.

Industry Feedback on FDA Proposals
Industry then gave additional feedback on FDA's Total Product Life Cycle Advisory (TAP) 2.0 proposal, requested clarity on current TAP staffing levels, and sought additional information about the roles and responsibilities of the current TAP advisors. Industry expressed opposition to FDA's proposed operational expenses and requested clarity from FDA on what these expenses would cover. Industry emphasized the need for meaningful metrics for TAP 2.0 moving forward and that the program should provide benefit across the device ecosystem, not just to TAP-designated products. Industry raised several points about program scope and eligibility criteria. This topic will require further discussion.

Information Technology (IT) Tools
In December, FDA presented their proposal on IT Tools focusing on building upon existing IT infrastructure to enhance efficiency and customer service. FDA explained their proposal to enhance submission processing through automation and to improve the customer experience during submission intake. FDA proposed enhanced portal functionality that will transform how they interact with official correspondents.

FDA explained the proposed Portal Communications capability can also support the communication needs of the Navigator Tool, which is intended to help sponsors identify the most appropriate resource or communication channel for their specific needs. FDA proposed to leverage and expand the portal communications capability for premarket submissions to provide a structured way for sponsors to interact with FDA on inquiries that aren't related to an ongoing premarket review.

Industry asked whether costs would continue beyond fiscal year 2032 and FDA indicated there will be ongoing maintenance costs but also a projected net savings in contractual costs. Industry asked whether these IT improvements would help with interactive review and FDA confirmed, noting that it also would create a more robust FDA record.

Industry committed to providing feedback on this proposal in an upcoming negotiation meeting.

Real World Evidence

During the January 21st negotiation meeting, Industry requested specifics on FDA's proposed Real World Evidence (RWE) investment regarding the full-time equivalents (FTEs) and operational dollars to better understand how the funds would be spent, how new data sources would be leveraged to support premarket review, as well as additional details about activities current FTEs are doing to support RWE. In response, FDA provided additional information during the negotiation meeting.

After FDA's presentation, Industry had questions about how the proposed operational dollars for data source development would complement the investment in NEST, and suggested a separate dialogue between Industry, FDA and NEST.

De Novo and Pre-Submissions

De Novo: Industry and FDA confirmed that previously both parties had come to agreement on all but one element of the De Novo proposal - committing to regular discussion meetings during the review cycle. After discussion, Industry indicated willingness to move forward with the proposal without including the commitment to mandated regular discussion meetings during the review cycle. FDA and Industry agreed to describe interactive review as best practice instead. FDA and Industry also agreed to implement a walkthrough meeting with the review team and the sponsor, to occur within the first 30 days of review.

Industry committed to providing feedback on this proposal in an upcoming negotiation meeting.

Pre-Submissions: Industry and FDA confirmed that previously both parties had come to agreement on all but two elements requiring further deliberation – faster feedback options and

bundling of traditional pre-submissions. FDA presented updates on behalf of the FDA-Industry working group in the meeting pertaining to these two elements.

FDA and Industry agreed to implement faster feedback options for certain pre-submissions. During the discussion, Industry requested minor updates to the character and page limits proposed by FDA, which FDA agreed to.

FDA and Industry agreed to not move forward with the bundling of traditional pre-submissions. Industry committed to providing feedback on this proposal in an upcoming negotiation meeting.

Operating Reserve and Trigger Reform

In the prior negotiation meeting, Industry presented an update on all FDA proposals, including on elements of the operating reserve and how FDA would seek industry alignment in allocating funding from the MDUFA carryover balance. In follow-up, FDA shared a modified proposal to provide direction in the MDUFA VI Commitment Letter on the use of carryover funds as well as set forth a process to provide greater transparency and engagement prior to certain funding decisions. Industry expressed receptivity but sought a few modifications, which FDA agreed to take back for consideration.

FDA proposed a modified proposal to the reform of the appropriations trigger to account for circumstances in which Congressional appropriations do not increase commensurate with the current provision. Industry asked clarifying questions and agreed to provide feedback on this proposal in an upcoming negotiation meeting.

Discussion & Recap

FDA rejected Industry's proposal to factor compliance with the United States-Mexico-Canada Agreement (USMCA) in setting foreign establishment fees. FDA and Industry agreed to continue discussions on other details of fee structure changes in a future negotiation meeting but not revisit USMCA.

Next Meeting: The next meeting is scheduled for February 18, 2026.

Meeting End Time: 12:55 pm EST